



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,589	07/01/2002	Toshio Ota	084335-0155	6330

22428 7590 05/16/2005

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
----------

LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
----------	--------------

1647

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/031,589	Applicant(s) OTA ET AL	
	Examiner Jon M. Lockard	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*pd*

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The Amendment filed 22 February 2005 has been received and entered in full. Claims 1 and 6-9 have been amended, and claims 3-4 and 10-16 have been cancelled. Therefore, claims 1-2 and 5-9 are pending and claims 1-2 and 5-9 are the subject of this Office Action.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections and/or Rejections***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file (Japanese application 11/209817, filed 23 July 1999), and the Examiner has acknowledged that "all" copies of the certified copies of the priority documents have been received in this National Stage application. However, should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application (Japanese application 11/209817, filed 23 July 1999) should be submitted under 37 CFR 1.55 in reply to this action.
4. The objection to the drawings as set forth at page 3 (§7) in the previous Office Action (mailed 21 September 2004) is withdrawn in view of Applicant's amendments (filed 22 February 2004).

Art Unit: 1647

5. The objection to the Specification as set forth at page 3 (§8) in the previous Office Action (mailed 21 September 2004) is withdrawn in view of Applicant's amendments (filed 22 February 2005).

6. The objection to claims 1-2 and 5-9 for encompassing non-elected inventions as set forth at page 4 (§9) in the previous Office Action (mailed 21 September 2004) is withdrawn in view of Applicants amendments (filed 22 February 2005).

7. The objection to claim 13 as set forth at page 4 (§11) in the previous Office Action (mailed 21 September 2004) is moot in view of Applicants cancellation of said claim (filed 22 February 2005).

8. The rejection of claims 3, 10, and 13-15 under 35 U.S.C. §101 as set forth at pages 5-8 (§12-20) in the previous Office Action (mailed 21 September 2004) is moot in view of Applicants cancellation of said claims (filed 22 February 2005).

9. The rejection of claims 3, 10, and 13-15 under 35 U.S.C. §112(1), Enablement, as set forth at page 8 (§21) in the previous Office Action (mailed 21 September 2004) is moot in view of Applicants cancellation of said claims (filed 22 February 2005).

10. The rejection of claims 1-3, 5-10, and 13-15 under 35 U.S.C. §112(1), Scope of Enablement, as set forth as pages 8-10 (§22-24) in the previous Office Action (mailed 21 September 2004) is withdrawn in view of Applicants amendment of claims 1 and 9 which now recite a specific polynucleotide (SEQ ID NO:3) and a specific polypeptide (SEQ ID NO:4), and cancellation of claims 3, 10, and 13-15 (filed 22 February 2005).

11. The rejection of claims 1-3, 5-10, and 13-15 under 35 U.S.C. §112(1), Written Description, as set forth at pages 10-13 (§25-31) in the previous Office Action (mailed 21

Art Unit: 1647

September 2004) is withdrawn in view of Applicants amendment of claims 1 and 9 which now recite a specific polynucleotide (SEQ ID NO:3) and a specific polypeptide (SEQ ID NO:4), and cancellation of claims 3, 10, and 13-15 (filed 22 February 2005).

12. The rejection of claims 1-3, 5-10, and 13-15 under 35 U.S.C. §112(2), as set forth at pages 13-15 (¶32-41) in the previous Office Action (mailed 21 September 2004) is withdrawn in view of Applicants amendment of claims 1, 6-7, and 9, and cancellation of claims 3, 10, and 14-15 (filed 22 February 2005).

13. The rejection of claims 1-3, 5-10, 13, and 15 under 35 U.S.C. §102(e) as being anticipated by Drmanac et al, as set forth at pages 15-16 (¶42-46) in the previous Office Action (mailed 21 September 2004) is withdrawn in view of Applicants amendment of claims 1 and 9 which now recite specific sequences, and cancellation of claims 3, 10, and 15 (filed 22 February 2005).

14. The rejection of claim 14 under 35 U.S.C. §103 as being unpatentable over Drmanac et al. in view of Maruyama et al., as set forth at pages 16-17 (¶47-53) in the previous Office Action (mailed 21 September 2004) is moot in view of Applicants cancellation of said claim (filed 22 February 2005).

### ***Maintained Objections and/or Rejections***

#### ***Claim Objections***

15. Claim 1 is objected to because of the following informalities: a “;” should be inserted between “3” and “and” in line 3 of the claim. Appropriate correction is suggested.

16. Claims 8 and 9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and cannot depend from any other multiple dependent claim. For unacceptable multiple dependent claim wording, see MPEP § 608.01(n) B. 3., for an example showing reference to two sets of claims to different features, and § 608.01(n) B. 4., for an example showing reference back to another multiple dependent claim.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

19. Claims 7-9 are rejected as being indefinite because it is unclear what is meant by the phrases “cell which expresses the polynucleotide... or the vector” in claim 7, “cell expressing the polynucleotide” in claim 8, and “cell expressing the vector” in claim 9. Since proteins are expressed by cells, it is unclear what is meant by the phrases “cell which expresses the polynucleotide... or the vector” in claim 7, “cell expressing the polynucleotide” in claim 8, and “cell expressing the vector” in claim 9. Thus, the metes and bounds of the claims cannot be determined.

***Claim Rejections - 35 USC § 101***

20. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

21. Claims 1-2 and 5-9 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility, for reasons set forth in the previous Office Action (mailed 21 September 2004).

22. The instant application discloses a polynucleotide set forth as SEQ ID NO:3 encoding a polypeptide set forth as SEQ ID NO:4. The specification asserts “analysis of a full-length cDNA provides valuable information” (page 2, line17) and are “extremely valuable in empirical analysis of gene function and in industrial application” (page 2, lines 19-20). However, the instant specification does not teach any physiologic ligands or functional characteristics of the novel polypeptide set forth in SEQ ID NO:4 or encoded by the disclosed nucleic acid set forth in SEQ ID NO:3. Further, the protein comprising SEQ ID NO:4 or encoded by said disclosed nucleic acid has never been expressed in a cell or organism or assayed for functional activity. The amino acid set forth in SEQ ID NO:4 has been deduced from the nucleic acid sequence (see page 4, lines 10-13). There is no well-established utility for a specific nucleic acid or amino acid sequence and the specification fails to disclose a specific and substantial utility for the claimed invention.

23. The Applicants point out that the Specification teaches that PSEC0043 (encoding SEQ ID NO:4) is a clone derived from NT-2 cells cultured in the presence of retinoic acid (See page 17, lines 18-19 and page 19, line 4). The Applicants also note that the Specification teaches the NT-

Art Unit: 1647

2 cell is neuron progenitor cell that can differentiate into neurons by treatment with retinoic acid (See page 17, lines 13-14). That Applicants argue at page 9 of the response (filed 22 February 2005) that the clone (PSEC0043, SEQ ID NO:4) can be used as a marker for identifying cells that differentiate into neurons by retinoic acid, and that such a marker is useful for the evaluation of neuron regeneration. Applicant's arguments filed 22 February 2005 have been fully considered but they are not persuasive for the following reasons. The utility of clone PSEC0043 (the polynucleotide of SEQ ID NO:3 which encodes the polypeptide of SEQ ID NO:4) as a marker for identifying cells that differentiate into neurons by retinoic acid, which is useful for evaluating neuron regeneration as argued at page 9 of the response (filed 22 February 2005) was not disclosed or asserted in the Specification as originally filed. Furthermore, the Specification has not taught whether or not the polynucleotide set forth as SEQ ID NO:3 is expressed in NT-2 cells that have not been treated with retinoic acid, or any other cell line or tissues, such that identification of such would be a marker for identifying cells that differentiate into neurons by retinoic acid.

24. It is believed that all pertinent arguments have been addressed.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph***

25. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

26. Claims 1-2 and 5-9 are also remain rejected under 35 U.S.C. 112, first paragraph for



Art Unit: 1647

reasons set forth at page 8 (§21) of the previous Office Action (mailed 22 September 2004).

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

27. The Applicants argue at page 9 of the response (filed 22 February 2005) that the claims now recite SEQ ID NO:3 and SEQ ID NO:4, which the Examiner indicated comply with the requirements for enablement. It is noted that the Examiner had rejected claims 1-3, 5-10, and 13-15 under 35 U.S.C. 112, first paragraph (Enablement), since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention as set forth at page 8 (§21) of the previous Office Action (mailed 21 September 2004), and had further rejected claims 1-3, 5-10, and 13-15 because the instant disclosure would not be found to be enabling for the full scope of the claimed invention as set forth at pages 8-10 (§21-24) of the previous Office Action (mailed 21 September 2004). Applicants amendment of the claims which now recite a specific polynucleotide (SEQ ID NO:3) and a specific polypeptide (SEQ ID NO:4) (filed 22 February 2005) are only sufficient to overcome the scope of enablement rejection, as set forth above.

### *Summary*

28. No claim is allowed.

Art Unit: 1647

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1647


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML  
May 5, 2005

  
**ROBERT S. LANDSMAN, PH.D.**  
**PRIMARY EXAMINER**